# EXHIBIT 9

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

PageID: 262158

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

TAMARA NEWSOME,

Plaintiff,

٧.

JOHNSON & JOHNSON, et al.,

Defendants.

MDL NO. 16-2738 (FLW) (LHG)

Civil Action No.3:18-cv- 17586-FLW-LHG

EXPERT REPORT OF CHERYL C. SAENZ, M.D.

Case-specific opinions regarding Ms. Tamara Newsome

Date: May 28, 2024

Cheryl C. Saenz, M.D.

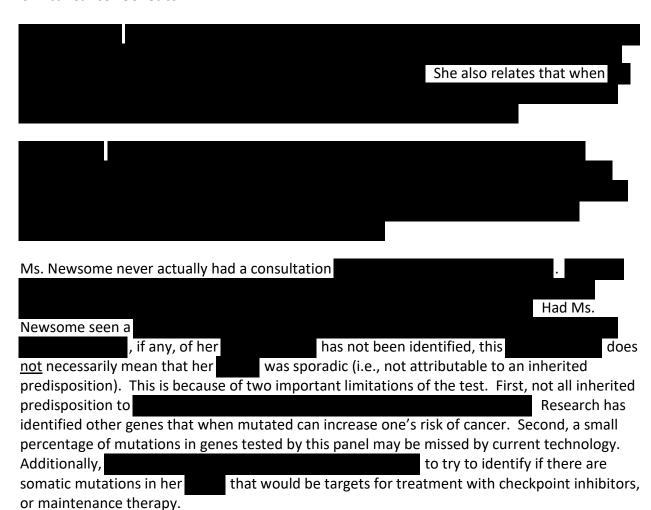
# **Diagnosis and Treatment of Ovarian Cancer**



<sup>&</sup>lt;sup>1</sup> NewsomeT-HCHMR-00151



#### **Clinical Cancer Genetics**



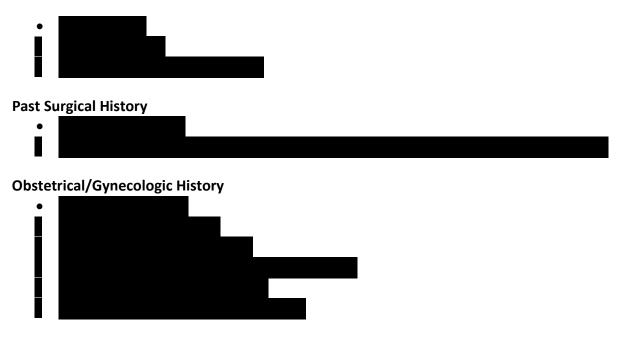
# **Past Medical History**

<sup>&</sup>lt;sup>2</sup> NewsomeT-MOHA-MDR-000017.

<sup>&</sup>lt;sup>3</sup> February 4, 2021 Deposition Transcript of Ravin Garg, MD, p. 115.

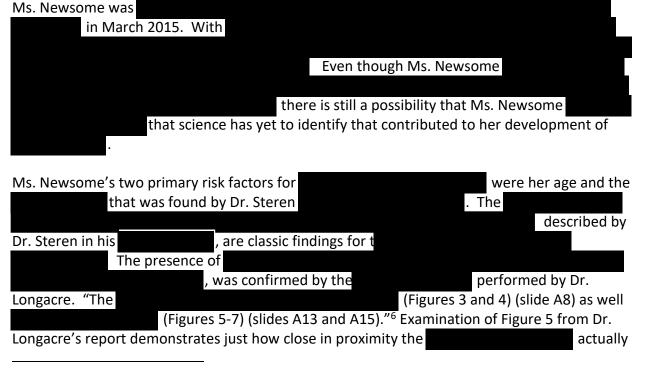
<sup>&</sup>lt;sup>4</sup> February 4, 2021 Deposition Transcript of Ravin Garg, MD, p. 55, lines 2-6.

<sup>&</sup>lt;sup>5</sup> February 17, 2021 Deposition Transcript of Albert Steren, MD, p. 55.

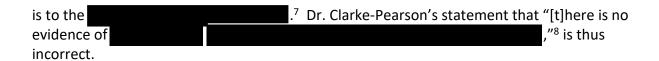


# Summary

I have performed a thorough review of Ms. Newsome's medical records, the depositions of Tamara Newsome, Daniel Francois, Jr., Tae'lor Francois, Ravin Garg, M.D., and Albert Steren, M.D., as well as the Plaintiff Profile Forms, expert reports of Drs. Godleski and Clarke-Pearson, and the depositions of Dr. Clarke-Pearson. I have also reviewed the expert report of Dr. Teri Longacre, defense expert in the field of gynecologic pathology.



<sup>&</sup>lt;sup>6</sup> February 11, 2022 Expert Report of Teri Longacre, MD, page 7.



Document 33369-12

PageID: 262162

As stated in my general causation report, the presence of endometriosis increases a woman's risk of developing endometrioid ovarian cancer by two - to threefold. That OR equates to a 100-200% increase in the risk of developing endometrioid ovarian cancer. Saavalainen and colleagues (2018), reported that women with ovarian endometriosis had an OR of 4.72 (2.75,7.56) of developing specifically endometrioid ovarian cancer, and even when the endometriosis was limited to the peritoneum there was still a twofold increase in the risk of endometrioid histology. Based on the surgical findings at the time of her well as the microscopic identification of , Ms. Newsome most likely carried the diagnosis of . Thereby, the presence of increased Ms. Newsome's risk somewhere in the range of 100 - 372%. Although of developing no distinct causal mechanism can be identified for Ms. Newsome's , as is the case with all individual patients who develop was most likely a substantial contributing factor. Dr. Steren, Ms. Newsome's gynecologic oncologist concurs, stating that "in most instances, the cause of ovarian cancer can't really be elucidated if they don't have a genetic predisposition." "We don't really know what causes them." 10

In his expert report Dr. Clarke-Pearson states that Ms. Newsome did not have any risk factors . At his deposition, however, he changed his opinion and for the development of contributed to her developing the disease, based on agreed that her Olsen et al. (2013) identified an OR of 1.37 increased risk of developing ovarian cancer in women with a BMI between 30.0-34.0.12 In his deposition, Dr. Clarke-Pearson characterizes an OR of 1.37 as only "a slightly increased risk of developing ovarian cancer." <sup>13</sup> He treats similar ORs associated with talc exposure very differently. In his expert report he writes that the "casecontrol studies show a 30-40% increased risk of EOC associated with genital talcum powder use,"14 and he asserts that this OR has demonstrated that genital use of talc can cause epithelial ovarian cancer. It is unscientific (and reflective of a results-driven approach) to state when applied to obesity an OR of 1.37 only slightly increases a woman's risk of developing ovarian cancer, and yet when it is the OR associated with the genital application of talc that talc is causal in the development of the disease.

<sup>&</sup>lt;sup>7</sup> February 11, 2022 Expert Report of Teri Longacre, MD, page 16.

<sup>&</sup>lt;sup>8</sup> July 2, 2021 Expert Report of Daniel Clarke-Pearson, MD, page 17.

<sup>9</sup> Saavalainen, L., et al. Risk of gynecologic cancer according to the type of endometriosis. Obstetrics & Gynecology. 2018; 131(6), 1095-1102.

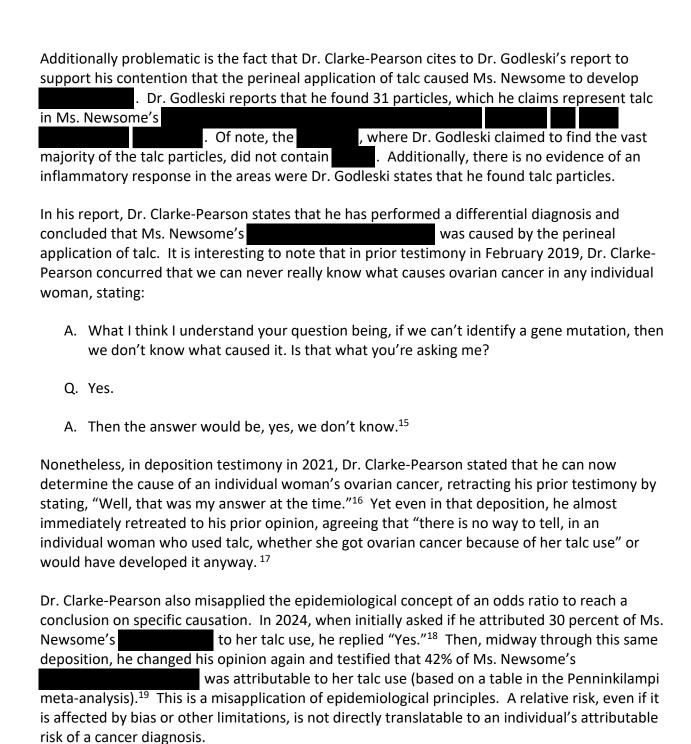
<sup>&</sup>lt;sup>10</sup> February 17, 2021 Deposition Transcript of Albert Steren, MD, p. 29, lines 13-17.

<sup>&</sup>lt;sup>11</sup> March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 321, lines 3-12.

<sup>&</sup>lt;sup>12</sup> Olsen C.M., Nagle, C.N., Whiteman, D.C., Ness R., Pearce C.L., Pike M., Rossing M.A., Terry K., Wu A., et al. (2013). Obesity and risk of ovarian cancer subtypes: evidence from the Ovarian Cancer Association Consortium. Endocr Relat Cancer, 20(2): 251-62.

<sup>&</sup>lt;sup>13</sup> March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 320, lines 9-18.

<sup>&</sup>lt;sup>14</sup> November 15, 2023 Amended Rule 26 Expert Report of Daniel Clarke-Pearson, MD, page 11.



Document 33369-12

PageID: 262163

<sup>&</sup>lt;sup>15</sup> February 4, 2019 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 94, lines 4-11.

<sup>&</sup>lt;sup>16</sup> August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 215, line 2.

<sup>&</sup>lt;sup>17</sup> August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 248 line 7-p. 249, line 2.

<sup>&</sup>lt;sup>18</sup> March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 306, lines 15-19.

<sup>&</sup>lt;sup>19</sup> Penninkilampi, R., & Eslick, G. D. (2018). Perineal Talc Use and Ovarian Cancer. *Epidemiology*, 29(1), 41-49.

Case 3:16-md-02738-MAS-RLS

Document 33369-12 PageID: 262164 Filed 10/16/24

Page 8 of 10

# Conclusion

While Ms. Newsome states that she used baby powder daily from 1975-2015 for hygiene purposes, there is no credible scientific data to support the conclusion that the talc contributed to her development of \_\_\_\_\_\_\_. The peer-reviewed scientific literature, nationally recognized and respected healthcare organizations (NCI, CDC, ACS, FDA), and the professional societies (SGO, ACOG) to which I belong, all maintain the position that talc does not cause ovarian cancer. All of the opinions herein are to a reasonable degree of medical probability. In addition, all of the general causation opinions contained in my General Expert Report dated May 21, 2024 are also incorporated herein.

# MATERIALS RELIED ON AND CONSIDERED BY DR. CHERYL SAENZ

# PLAINTIFF PROFILE FORM

1. 07/08/2020 Plaintiff Profile Form of Tamara Newsome

# **EXPERT REPORTS**

- 06/24/2021 Expert Report of John Godleski, MD
- 2. 07/02/2021 Expert Report of Daniel Clarke-Pearson, MD
- 3. 02/11/2022 Expert Report of Teri Longacre, MD
- 4. 11/15/2023 Amended Rule 26 Expert Report of Daniel Clarke-Pearson, MD

# **DEPOSITION TRANSCRIPTS**

- 1. 02/04/2019 Deposition Transcript of Daniel Clarke-Pearson, MD
- 2. 12/09/2020 Deposition Transcript of Tamara Newsome
- 3. 02/04/2021 Deposition Transcript of Ravin Garg, MD
- 4. 02/17/2021 Deposition Transcript of Albert Steren, MD
- 5. 05/13/2021 Deposition Transcript of Daniel François, Jr.
- 6. 05/14/2021 Deposition Transcript of Tael'lor Amelia Francois
- 7. 08/26/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 1)
- 8. 08/27/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 2)
- 9. 01/17/2024 Deposition Transcript of Daniel Clarke-Pearson, MD
- 10. 03/08/2024 Deposition Transcript of Daniel Clarke-Pearson, MD

## **MEDICAL RECORDS**

- 1. AAMC Oncology and Hematology (NewsomeT-AAMCOH-00007-00327)
- 2. Annapolis Oncology Center (NewsomeT-AOCMR-00001-00280)
- 3. Anne Arundel Medical Center (NewsomeT-AAMC-00001-00008; NewsomeT-AAMCMR-00006-00493; NewsomeT-AAMCRad-00019-00022)
- 4. Capital Women's Care (NewsomeT-CWCMR-00001-00103)
- 5. Community Radiology Associates (NewsomeT-CRAMR-00001-00011)
- 6. Holy Cross Hospital (NewsomeT-HCHMR-00001-00405; NewsomeT-HCHPath-00008-00113; NewsomeT-HolyCrossHospPath-00001-00007; NewsomeT-HCHRad-00001-00014)
- 7. Muttah, Sureshkumar, MD (NewsomeT-SMMLMR-00001-00027)
- 8. Myraid Genetics (NewsomeT-MGIMR-00001-00018)
- 9. Plaintiff Produced Medical Records (NEWSOMET AAMC C MDR000001-410; NEWSOMET C CAPI MDR000001-100; NEWSOMET CAPI MDR000001-23; NEWSOMET GARG C MDR000001-101; NEWSOMET GARG MDR000001-76;

NEWSOMET HCH MDR000001-43; NEWSOMET MOHA MDR000001-2; NEWSOMET MUTTATH C MDR000001-81; NEWSOMET MUTTATH MDR000001-80; NEWSOMET PWHS MDR000001-3; NewsomeT-MOHA-MDR-000003-000029; NEWSOMET-REC00001-10; NewsomeT-WHSMR-00001-00020; NewsomeT-PPR-00085-00296)

- 10. Quest Diagnostics (NewsomeT-QDNISJC-00001-00058)
- 11. Supervalu Pharmacy (NewsomeT-SFP-00001-00023; NewsomeT-SPCO-00001-00023)
- 12. Target Compliance (NewsomeT-TPCO-00001-00006)
- 13. Washington Adventist Hospital (NewsomeT-WAHMR-00001-00075; NewsomeT-WAHMRPharm-00006-00020; NewsomeT-WAHRad-00001-00004)
- 14. White Oak Medical Center (NewsomeT-WOMCMR-00006-00088; NewsomeT-WOMCRad-00002-00007)
- 15. Women's Health Specialists of Montgomery County (NewsomeT-WHSMCLMR-00001-00019; NewsomeT-WHSMCLMR-00025-00098)

#### **L**ITERATURE

- 1. Olsen C.M., Nagle, C.N., Whiteman, D.C., Ness R., Pearce C.L., Pike M., Rossing M.A., Terry K., Wu A., et al. (2013). Obesity and risk of ovarian cancer subtypes: evidence from the Ovarian Cancer Association Consortium. Endocr Relat Cancer, 20(2): 251-62.
- 2. Penninkilampi, R., & Eslick, G. D. (2018). Perineal Talc Use and Ovarian Cancer. *Epidemiology*, 29(1): 41-49.
- 3. Saavalainen, L., Lassus H., But A., Tiitinen A., Harkki P., Gissler M., Pukkala E., Heikinheimo O. (2018). Risk of gynecologic cancer according to the type of endometriosis. Obstetrics & Gynecology. 131(6): 1095-1102.

# **ADDITIONAL MATERIALS**

1. Saed Confidential Documents (SAED SEPT222021 SUPPL 000001-399)